

Amendment No. 1 to HB0572

Sexton C
Signature of Sponsor

AMEND Senate Bill No. 984

House Bill No. 572*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Section 53-10-203, is amended by adding the following subdivisions to be appropriately designated:

() “Biological product” has the same meaning as defined in 42 U.S.C. § 262(i);

() “Interchangeable biological product” means:

(A) A biological product licensed by the federal food and drug administration and determined to meet the safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4); or

(B) A biological product determined by the federal food and drug administration to be therapeutically equivalent as set forth in the latest edition or supplement of the federal food and drug administration’s “Approved Drug Products with Therapeutic Equivalence Evaluations,” also known as the “Orange Book”;

SECTION 2. Tennessee Code Annotated, Title 53, Chapter 10, Part 2, is amended by adding the following new section:

(a) A prescriber shall allow for substitution with an interchangeable biological product of a prescribed biological product under all circumstances unless:

(1) The prescriber determines the medical necessity of a prescribed biological product due to:

(A) An adverse reaction previously experienced by the patient to an interchangeable biological product;

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(B) An interchangeable biological product having previously been demonstrated as ineffective for the patient; or

(C) Any other clinically based, prescriber-determined need; or

(2) An interchangeable biological product is not available.

(b) If the prescriber determines a prescribed biological product is medically necessary for a patient, the prescriber shall, in the prescriber's own handwriting, place the instructions showing intent upon the prescription at the time it is prepared and issued. For the purposes of this subsection (b), "instructions showing intent" includes, but is not limited to, the following language:

(1) "Brand name medically necessary," "dispense as written," "medically necessary," "brand name," or "no generic";

(2) Any abbreviation of the language in subdivision (b)(1); or

(3) Any other prescriber handwritten notation, such as circling a preprinted instruction to dispense as written on the prescription order, that clearly conveys the intent that a brand name is necessary for this patient.

(c) If the prescriber determines that a prescribed biological product is medically necessary for a patient and the prescription order is issued orally, the prescriber shall alert the pharmacist that use of the prescribed biological product is medically necessary for the patient.

(d) If the prescriber determines that a prescribed biological product is medically necessary for a patient and the prescription order is issued by the prescriber in the form

of an electronic prescription order or facsimile prescription order, the prescriber shall place, or cause to be placed, the proper instruction on the electronic prescription order or facsimile prescription order prior to it being transmitted to the pharmacist.

(e) Nothing in this section shall prevent a prescriber or dispenser from informing a patient of the prescriber or dispenser's professional opinion as to the capabilities, effectiveness, and acceptability of any biological product.

(f) A pharmacist who selects an interchangeable biological product for substitution, pursuant to this section, has the same responsibility for the selected product as the pharmacist would in dispensing a prescription for the product prescribed.

(g) The manufacturer, packager, or distributor of any human use legend drug or biological product sold, delivered, or offered for sale in this state shall have printed on the label of the immediate container of the biological product the name and address of the manufacturer, packager, or distributor of the finished dosage form of the biological product.

(h) The pharmacist shall notify the patient of the substitution with an interchangeable biological product by noting the substitution on the prescription label.

(i) Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in an interoperable electronic medical records system, through an electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber, or as set forth in a collaborative pharmacy practice agreement as defined in § 63-10-204; otherwise, the pharmacist or the pharmacist's designee shall communicate to the prescriber the biological product dispensed to the patient, using facsimile, telephone,

electronic transmission, or other prevailing means; provided, that communication shall not be required where:

(1) There is no FDA-approved interchangeable biological product for the product prescribed; or

(2) A prescription is not changed from the product dispensed on the prior filling of the prescription.

(j) This section shall not apply to prescriptions dispensed for inpatients of a hospital, a nursing home, or an assisted-care living facility, as defined in § 68-11-201.

(k) The notification and communication requirements in this section shall not apply to vaccines.

(l) The board of pharmacy shall maintain a link on its web site to the current list of all biological products determined by the federal food and drug administration to be interchangeable biological products.

(m) The pharmacist shall maintain a record of the biological product dispensed as required pursuant to § 53-14-110.

SECTION 3. This act shall take effect upon becoming a law, the public welfare requiring it.